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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,730	12/18/2001	Y. Tom Tang	PF-0635-2 DIV	8039

22428 7590 10/04/2004

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/025,730	TANG ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11 and 58-72* is/are pending in the application.

4a) Of the above claim(s) *60,62,71 and 72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 58-59, 61 and 63-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 9/13/04, is acknowledged.

2. Claims 11 and 58-72 are pending.

3. Claims 60, 62, 71 and 72 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

4. Claims 11, 58-59, 61 and 63-70 are under consideration in the instant application as they read on an antibody which specifically binds to a polypeptide compring amino acid of SEQ ID NO: 1, fragments and composition thereof.

5. In view of the amendment filed on 9/13/04, only the following rejection are remained.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 11, 64, 67, 69 and 70 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Miyamoto *et al* (Mol Reprod Dev. 34(1):1-7, 1993) in view of Alisa Campbell (General properties and applications of monoclonal antibodies, Elsevier Science Publishers, 1984, section 1.1), as is evidanced by Bost *et al.* (Immunol. Invest. 1988; 17:577-586) for the same reasons set forth in the previous Office Action mailed 5/11/04.

Applicant's arguments, filed 9/13/04, have been fully considered, but have not been found convincing.

Applicant points to the MPEP 1212 which state that an "examiner must provide a rational or evidence tending to show inherency." However, "the fact that a certain result or characteristic ***may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.*** In re Rijchaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). Applicant further

states that "to establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is ***necessarily present*** in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, ***may not be established by probabilities or possibilities. There mere fact that a certain thing may result from a given set of circumstances is not sufficient***."" Applicant further states that "in relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art". Applicant argues that the mere fact that antibodies to the protein disclosed by Miyamota et al may cross-react with a polypeptide of SEQ ID NO:1 is insufficient to establish inherency. Applicant goes on to argue that to establish inherency, antibodies to the protein disclosed by Miyamota et al must always cross-react with the polypeptide of amino acid sequence SEQ ID NO: 1. But the Examiner has not established this fact.

Although the reference is silent about the antibody binding to SEQ ID NO: 1, the high homology of the sequences (80%) would allow for cross-reactivity of the polyclonal/monoclonal antibodies. Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibodies do not bind to SEQ ID NO: 1 as recited in the claims. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980). In addition, applicant is invited to consider the following decisions based upon generating antibodies. Whether the rejection is based on "inherence" under 35 U.S.C. § 102 or prima facie obviousness under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. Examiner properly shifted burden to applicant to establish, through objective evidence, that hybridoma and monoclonal antibody of invention differ in unobvious manner from those of the prior art references. Ex parte Phillips, 28 USPQ2d 1302 (BPAI 1993). Here, applicant has not provided any objective evidence to support the difference between the prior art and instant antibodies. The record does not contain sufficient objective evidence that the referenced antibodies differ in any significant manner from that claimed.

Applicant argues that MO25 protein is not identical to a polypeptide of SEQ ID NO:1, the two proteins having only approximately 80% amino acid identity. Applicant draws the Examiner's attention to page 4 of the Office Action dated 5/11/04 that "Colman et al teach single amino acid changes in an antigen can effectively abolish antibody antigen binding activity" and that " Lederman et al disclose that a single amino acid substitution in a common allele ablates binding of a monoclonal antibody".

The Examiner recognizes that the dual rejections under the prior art and under enablement may appear to put the applicant in what he may consider to be an untenable position, especially given the fact situation presented here, where the teachings of the specification appear to be commensurate with the teachings of the prior art. It is this type of circumstance, however, that it is especially important for the examiner to make both the enablement rejection and the art

rejection of record. When both rejections are made from the beginning, however, the applicant knows where the issues lie and can focus his or here resources on demonstrating why the teachings of the specification go beyond the teachings of the prior art. It is proper for the examiner to make the superficially inconsistent art and enablement rejections, and place the burden on applicant to distinguish his or her specification from the prior art and to point out how the specification goes beyond and elaborates upon what is taught by the previously published reference. Therefore, the teachings of both Colman et al and Lederman et al were used for the enablement rejection which may appear to be inconsistent with the art rejection, however, such rejections are proper as explained supra.

Applicant argues that the Examiner has not established that the identical fragments comprise identical epitopes of MO25 and SEQ ID NO: 1 to which antibodies will cross-react.

Since the office does not have a laboratory to test the reference antibodies, it is applicant's burden to show that the reference antibody does not bind to the SEQ ID NO:1 recited in the claims. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); and In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

7. Claims 63 and 66 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Miyamoto *et al* (Mol Reprod Dev. 34(1):1-7, 1993) in view of Alisa Campbell (General properties and applications of monoclonal antibodies, Elsevier Science Publishers, 1984, section 1.1), as is evidanced by Bost *et al.* (Immunol. Invest. 1988; 17:577-586), as applied to claims 11, 64, 67, 69 and 70 above, and further in view of Harlow (1989) for the same reasons set forth in the previous Office Action mailed 5/11/04.

Applicant's arguments, filed 9/13/04, have been fully considered, but have not been found convincing.

Applicant lump the arguments of 103(a) rejections under the subtitle Rejections under 35 U.S.C 103(a), therefore the Examiner position is same as above.

8. Claim 58 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Miyamoto *et al*, in view of Alisa Campbell, as is evidanced by Bost *et al*, as applied to claims 11, 64, 67, 69 and 70 above, and further in view of Owens *et al* (1994) for the same reasons set forth in the previous Office Action mailed 5/11/04.

Applicant's arguments, filed 9/13/04, have been fully considered, but have not been found convincing.

Applicant lump the arguments of 103(a) rejections under the subtitle Rejections under 35 U.S.C 103(a), therefore the Examiner position is same as above.

9. Claim 59, 61, 65 and 68 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Miyamoto *et al* in view of Alisa Campbell, as is evidanced by Bost *et al.*, as applied to claims 11, 64, 67, 69 and 70 above, and further in view of U.S. Patent No. 6,210,675 for the same reasons set forth in the previous Office Action mailed 5/11/04.

Applicant's arguments, filed 9/13/04, have been fully considered, but have not been found convincing.

Applicant lump the arguments of 103(a) rejections under the subtitle Rejections under 35 U.S.C 103(a), therefore the Examiner position is same as above.

10. No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maher Haddad, Ph.D.
Patent Examiner
September 24, 2004

Christina Chan

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